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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,397	03/31/2006	Kinya Takagaki	NANP130US	5897

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EXAMINER
GOON, SCARLETT Y

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
09/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/574,397	TAKAGAKI ET AL.	
	Examiner	Art Unit	
	SCARLETT GOON	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *31 March 2006 and 21 June 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendment filed on 31 March 2006 in which claims 3-6 were currently amended, and claims 7-13 were newly added, is acknowledged.

Claims 1-13 are pending in the instant application.

Priority

This application is a National Stage entry of PCT/JP2003/012620 filed on 1 October 2003.

Information Disclosure Statement

The information disclosure statements (IDS) dated 31 March 2006 and 21 June 2006 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609, unless otherwise noted. Accordingly, they have been placed in the application file and the information therein has been considered as to the merits.

References JP 63-162685 and JP 06-049053 on the IDS dated 21 June 2006 are deleted because they are duplicates of references listed on the IDS dated 31 March 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "proanthocyanidin-containing product" renders the claim herein indefinite. It is unclear because it does not set forth the metes of bounds of what the product actually encompasses. One of ordinary skill in the art would not be able to ascertain what other structural units, if any, are present in the compound.

The recitation of "…not more than 90 Å or not less than 100 Å…" in claim 5 renders the claim herein indefinite. The recitation does not set forth the metes and bounds of the claimed pore radius because the upper and lower limits are not defined. Hence, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-13 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S Patent No. 6,126,940 to Takahashi *et al.* (herein referred to as the '940 patent, PTO-892, Ref. A).

The Takahashi '940 patent discloses a hair-growing agent comprising proanthocyanidin as the active ingredient and a method of extracting and purifying proanthocyanidin from plants. Proanthocyanidin indicates a group of polymer compounds composed of constitutive units of flavan-3-ol derivatives of formula (I) (column 1, lines 40-57). It is preferable that the proanthocyanidin used as the active ingredient in the hair-growing agent is a dimer or a trimer (column 2, line 66 – column 3, line 14). Proanthocyanidin can be extracted from various plants such as grape, kaki, betel palm, apple, barley, Nest-leaf, rhubarb, cinnamon, adzuki bean, raspberry, etc., or it can be chemically synthesized (column 3, lines 15-19). Extracted proanthocyanidin can be purified by any known method of separating and purifying herb. It is preferable to employ a two-phase solvent partitioning method, a column chromatographic method and a partitioning high-performance liquid chromatographic method or the like, singly or combined (column 3, lines 57-63). The column chromatographic method includes an ion-exchange column chromatographic method of using Amberlite IR-120B, Amberlite IRA-402, an adsorption column chromatographic method of using a normal phase silica gel, a reversed phase silica gel, Diaion HP-20, Sepabeads SP-207, a gel permeation method of using Sephadex LH-20, etc (column 4, lines 1-7). The chromatographic methods can be used singly or combined for repeated purification (column 4, lines 7-8).

A method of extracting and purifying a proanthocyanidin dimer is exemplified in Referential Example 1 (column 7, lines 1-45). Epicatechin-(4β→8)-catechin was extracted from the seeds of betel nuts. The extract was then passed through a column filled with Diaion HP-20 adsorbent (column 7, lines 16-19). The column loaded with the

extract was then washed with 10% (v/v) methanol to remove non-adsorbed material followed by elution with 2.5 liters of 30% (v/v) methanol and 1.25 liters of 30% (v/v) methanol (column 7, lines 21-24). The eluate was then concentrated under pressure and passed through a second column filled with Sephadex LH-20 (column 7, lines 26-29). The Sephadex LH-20 column loaded with concentrated eluate from the Diaion HP-20 column was then washed with 5.2 liters of 50% (v/v) methanol and 2.6 liters of 75% (v/v) methanol to remove non-adsorbed material, followed by elution with 1.3 liters of 75% (v/v) methanol (column 7, lines 30-33). The obtained material was subjected to partitioning by high-performance liquid chromatography to yield the purified epicatechin-(4β→8)-catechin product. The Takahashi '940 patent also discloses the purification of a proanthocyanidin trimer in Referential Example 3 using a similar method (column 8, lines 24-67).

It is noted that the Takahashi '940 patent does not disclose that the adsorbents used are porous, nor does the reference disclose what size compounds the resin is capable of purifying. However, as evidenced by www.diaion.com (PTO-892, Ref. U), Diaion HP-20 is an aromatic synthetic porous adsorbent with a pore radius of 200-300 Å. Furthermore, its recommended usage is for purifying compounds with molecular weights less than several tens of thousands. Thus, these features are an inherent property of the Diaion HP-20 adsorbent. Furthermore, as evidenced by Sigma, Sephadex LH-20 is a crosslinked dextran-based resin (PTO-892, Ref. V). Thus, the make-up of Sephardex LH-20 is an inherent property of the resin.

Therefore, the method of extracting proanthocyanidin dimers and trimers from various plants, followed by purification of the compounds on both a Diaion HP-20 column and a Sephadex LH-20 column, disclosed in the Takahashi '940 patent, anticipates instant claims 1-13.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCARLETT GOON whose telephone number is 571-270-5241. The examiner can normally be reached on Mon - Thu 7:00 am - 4 pm and every other Fri 7:00 am - 12 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

/SCARLETT GOON/
Examiner
Art Unit 1623